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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,173	07/09/2004	Henryk Struszczyk	7008USO1	6041

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,173	STRUSZCZYK ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goosen et al (US Patent No. 4,942,129) in view of Struszczyk et al (US Patent No. 5,554,445).

Applicant claims a chitosan-calcium (II) complex, comprising: calcium (II) ions bound to a gel of a chitosan salt, wherein said complex contains ≥ 0.5 wt% chitosan having an average molecular weight ≥ 10 kD, a polydispersity ≥ 2.0, deacetylation degree ≥ 65% and wherein said complex has a water retention value ≥ 300%, pH ≤ 6.9

and a calcium ion content ≥ 0.1 wt% relative to chitosan. Additional limitations in the dependent claims include the chitosan-calcium complex wherein said calcium (II) ions are bound with the chitosan gel by coordinate bonds or hydrogen bonds; and the chitosan-calcium (II) complex wherein said complex is water soluble. Applicants also claim a method to produce a chitosan-calcium complex from a gel of a chitosan salt comprising the steps of: (a) providing a suspension containing ≥ 0.01 wt % chitosan gel, said gel having an average molecular weight ≥ 10 kD, a polydispersity ≥ 2.0, deacetylation degree ≥ 65%; and b) mixing said chitosan gel with ≥ 0.01 wt% calcium (II) salt to form said complex; wherein said complex has a water retention value ≥ 300% and a pH ≤ 6.9. Additional limitations in the dependent claims of the claimed method include said calcium salt being selected from the group consisting of calcium chloride and calcium acetate; calcium (II) salt concentration being 10 to 50 wt% relative to chitosan; mixing step being carried out at a temperature ≥ 10°C.

The Goosen et al patent discloses penetration of chitosan into a calcium alginate gel matrix to form chitosan-alginate microcapsules using chitosan derivatives having a molecular weight (MW) greater the 10 kD and pH of 6.5 (see column 11, 2nd paragraph), which fall within the MW and pH ranges disclosed in the instant claims.

The chitosan-calcium (II) complex of the instant claims differ from the chitosan-alginate gel matrix of the Goosen et al patent by claiming additional properties of the chitosan which include the polydispersity being ≥ 2.0, deacetylation degree being ≥ 65% and water retention value being ≥ 300%.

The Struszczyk et al patent shows that the polydispersity, deacetyation degree and water retention values disclosed for chitosan in the instant claims are well known in the art. See Example 1 of the Struszczyk et al patent wherein microcrystalline chitosan is characterized as having an average molecular weight of 78000, deacetylation degree of 72%, and water retention value of 1240%.

One of ordinary skill in this are would be motivated to combine the teachings of Goosen et al patent with that of the Struszczyk et al patent since both patents disclose chitosan product used in the preparation of membranes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the chitosan product used to prepare chitosan-alginate microcapsules of the Goosen et al patent with the microcrystalline chitosan having an average molecular weight of 78000, deacetylation degree of 72%, and water retention value of 1240% in view of the recognition in the art, as evidenced by the Struszczyk et al patent, that the chitosan product thereof increases the effectiveness of chemicals by reducing the dosage of dressing chemicals as well as their losses into the environment.

3. Claims 10-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nies et al (EP 650999 A1) in view of Hashimoto et al (U.S. Patent No. 5,474,989).

Applicants claim method of preparing chitosan salt gels, comprising the steps of: (a) degrading chitosan in an aqueous acidic solution with enzymes, said solution having a chitosan concentration of ≥ 0.5 wt% for a desired time and at a desired temperature; (b) deactivating said enzymes after said desired time is completed; (c) adding an aqueous basic solution to said enzyme/aqueous chitosan mixture to attain $4.0 \leq pH \leq 6.0$; and (d) continuously mixing said mixture until a gel of a chitosan salt forms. Applicants also claim a method of preparing a gel of a chitosan salt, comprising the steps of: (a) degrading chitosan hydrolytically, said chitosan being dissolved in an aqueous acidic solution, said solution having a chitosan concentration of ≥ 0.5 wt% for a desired time and at a desired temperature; (b) adding an aqueous basic solution to the mixture of step (a) to attain $4.0 \leq pH \leq 6.0$; and (c) continuously mixing the product of step (b) until a gel of a chitosan salt forms. Applicants further claim a method of pepar-ing a chitosan salt gel, comprising the steps of: (a) degrading chitosan with an oxidizing agent, said chitosan being dissolved in an aqueous acidic solution, said solution having a chitosan concentration of ≥ 0.5 wt% for a desired time and at a desired temperature; (b) adding an aqueous basic solution to the mixture of step (a) to attain $4.0 \leq pH \leq 6.0$; and (c) continuously mixing the product of step (b) until a gel of a chitosan salt forms. Additional limitations in the dependent claims include gels forming at a specific pH; the aqueous acidic solution comprising a specific acid; the basic solution comprising a specific base as a specific concentration; the chitosan used at a specific concentration;

the degrading step carried out at a specific temperature; and method carried out using a batch process.

The Nies et al publication discloses production of gels of chitosan effected by dissolving the chitosan and an acid chelate complex in water, wherein gels are obtained by adding to the solution polyvalent metal/acid salts in which the chitosan is only slightly soluble (see Derwent Abstract). The abstract discloses the salts used in the production of the chitosan gels may be selected as calcium -carbonate, -sulphate, -phosphate or -oxalate.

The instantly claimed methods differ from the method of the Nies et al publication by claiming a step of degrading chitosan that involves degrading chiosan with enzymes, degrading chitosan hydrolytically, and degrading chitosan with an oxidizing agent.

The Hashimoto et al patent shows that the degradation of chitosan is well known in the art. The Hashimoto et al patent teaches methods of obtaining low molecular weight chitosan which include enzyme treatment of chitosan, and subjecting chitosan to treatment with compounds such as hydrogen peroxide (an oxidizing agent), nitrite ion, an alkali or an acid (see column 2, lines 63-67). The step of degrading chitosan in the instant claims is within the scope of reducing the molecular weight of chitosan. See column 3, line 17, wherein chitinase or chitosanase may be selected as the enzymes to cause degradation of the chitosan's molecular weight.

One of ordinary skill in this art would be motivated to combine the teachings of the Nies et al publication with the teachings of the Hashimoto et al patent since both documents teaches the preparation of drug compositions comprising chitosan.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of preparing a chitosan salt gel of the Nies et al publication a process step that degrades or lower the molecular weight of the chitosan in view of the recognition in the art, as evidenced by Hashimoto et al patent, that the dissolution rate of pooly water-soluble drugs were improved by mixing the poorly water-soluble drugs with a low molecular weight chitosan.

Summary

4. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

E. White

9/17/06

Shaojia A. Jiang
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